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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/541,499

07/07/2005

Hisakazu Hojo

050412

2008

23850 7590 09/30/2009
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EXAMINER

BEKKER, KELLY JO

ART UNIT

PAPER NUMBER

1794

MAIL DATE

DELIVERY MODE

09/30/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/541,499	Applicant(s) HOJO ET AL.	
	Examiner KELLY BEKKER	Art Unit 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Amendments made 7/29/09 have been entered.
Claims 1-3 and 5-12 remain pending.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 29, 2009 has been entered.

Claim Rejections - 35 USC § 112 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The 112 2nd paragraph rejections of claims 2-12 as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, specifically for the recitation of "wherein a content of said component (B) is not less than 20% by weight of the total amount of the components (B) and (D)" has been withdrawn in light of applicant's amendments made July 29, 2009.

The following 112 2nd paragraph rejections of claim 5 is necessitated by applicant's amendments filed July 29, 2009.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 depends on claims 1 or 2 and recites a list of chelating agents which the chelating agent is selected from. Claims 1 and 2 also recite a list of chelating agents which the chelating agent is selected from. The list of chelating agents recited in claim

5 includes additional chelating agents, such as gluconates, which are not included in the list of chelating agents recited in claims 1 and 2, thus claim 5 contradicts with the claim limitations of claims 1 and 2 and it is unclear as to which chelating agents are encompassed and not encompassed by the instantly claimed invention.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The 103(a) rejection of claims 1-3 and 5-12 over Hojo et al. (US 6254905 B1) in view of the combination of Grossman (About.com, "Facts About Iron" pages 1-5 <http://ibdcrohns.about.com/cs/nutrition/a/fdairon.html>) and Klahorst ("Calcium, An Important Nutrient" pages 1-5 http://www.ifanca.org/newsletter/2001_05.htm) has been withdrawn.

Claims 1-3 and 5-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hojo et al. (US 6254905 B1) in view of the combination of Koumarianos (US 6488957) and Grossman (About.com, "Facts About Iron" pages 1-5 <http://ibdcrohns.about.com/cs/nutrition/a/fdairon.html>) and Klahorst ("Calcium, An Important Nutrient" pages 1-5 http://www.ifanca.org/newsletter/2001_05.htm).

Hojo et al. (Hojo) teaches of a food additive composition which contains 100 parts by weight of calcium carbonate, i.e. a hardly water soluble inorganic compound with a solubility in water at 20C of not more than 0.1g/100g of water (Column 3 lines 50-58), 1-60 parts gum arabic (Column 3 lines 50-58) and an additive including the stabilizer sucrose fatty acid esters having a hydrophilic-lipophilic balance of not less than 8, wherein the gum arabic is not less than 20% by weight of the gum arabic and sucrose fatty acid esters combined (Column 4 lines 1-8). Hojo teaches that the composition contains 1-60 parts gum arabic and stabilizers total, wherein the gum arabic comprises most preferably about 55-100% of the composition, thus the stabilizer additive is included at 0-27 parts (0-45% of the 1-60 parts) and the gum arabic is included at 0.55-60 parts (55-100% of the 1-60 parts) in the composition as taught by

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Hojo. Hojo teaches that the food additive may contain ferrous gluconate or sodium iron citrate i.e. a gluconate or citrate chelating agent as instantly claimed (Column 11 lines 4-8). Hojo teaches that the inorganic compound, i.e. the calcium agent, has particle size of 0.8um or less (Column 9 lines 25-26). Hojo teaches that the food additive may be used, and thus contained in black tea or coffee (Column 10 line 66 through Column 11 line 3). Regarding an ingredient in the food as derived from vegetables as recited in claim 12, as Hojo teaches that the food additive is included in tea and as tea was known to be derived from tea leaves, i.e. known vegetables, one of ordinary skill in the art would expect that Hojo teaches that a portion of the food is derived from vegetables as recited in claim 12. Furthermore, it would have been obvious for the food product to be derived from vegetables so that the final product would contain the known benefits, such as nutritional benefits, from vegetables.

Hojo is silent to the amount of the ferrous gluconate, sodium iron citrate or chelating agent in the additive composition as recited in claims 1 and 2, and to the calcium ion concentration as 0-10, wherein the calcium ion concentration is obtained by adjusting a solid matter concentration of calcium to 10% by weight after pulverization and/or dispersion as recited in claim 8.

Koumarianos teaches of a food additive composition (abstract). Koumarianos teaches that the food additive composition contains minerals, including iron and that the amount of the mineral in the food additive composition is determined based on the recommended daily dosage (Column 5 lines 8-17).

Grossman teaches that the recommended daily amount of iron in 2001 for males ranged from 8-11mg per day and for females 8-18 mg per day. (page 3)

Klahorst, page 2, teaches that the recommended daily amount of calcium in 2001 was 1000-1300 mg per day.

Regarding the amount of the ferrous gluconate and sodium iron citrate or chelating agent in the additive composition as recited in claims 1 and 2, ferrous gluconate and sodium iron citrate were known food supplements that were sources of iron. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include an amount of the ferrous gluconate and/or sodium iron

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citrate and thus an amount of chelating agent in the additive composition depending on the recommended daily amounts of iron and the amount of iron desired in the final composition as taught by Koumarianos. It would have been further obvious to one of ordinary skill in the art at the time the invention was made for the vitamins and minerals in the food additive, including calcium and iron, to be included in the full recommended daily amounts so that when consuming the food additive the consumers would not be required to take other additives to obtain complete daily fulfillment of the said vitamins and minerals. Thus, one would have been further motivated to include an amount of iron to calcium in the nutritional additive composition based upon the recommended daily amounts of iron and calcium, so that the nutritional additive would fulfill the requirements for both minerals simultaneously; and as the RDA of calcium: iron was 1300:8 or 100:0.6 to 1000:18 or 100:1.8 as taught by Grossman and Klahorst, at the time the invention was made, one would have been motivated to include 0.6-1.8 parts of ferrous gluconate and/or sodium iron citrate, i.e. an iron source, per 100 parts of calcium carbonate, i.e. a calcium source. Thus, the composition as taught by Hojo would comprise 0.6-1.8 parts of ferrous gluconate and/or sodium iron citrate which are chelating agents as instantly claimed.

Regarding the calcium ion concentration as 0-10, wherein the calcium ion concentration is obtained by adjusting a solid matter concentration of calcium to 10% by weight after pulverization and/or dispersion, Hojo (Column 8 lines 34-43) teaches that the calcium ion concentration is balanced for stability and preventing damage of the proteins and gelling of the food composition. Hojo teaches that too little can cause instability and that too much can cause damage to the food proteins and gelling. Hojo teaches that the calcium ion concentration as about 10-500, wherein the calcium ion concentration is obtained by adjusting a solid matter concentration of calcium to 10% by weight after pulverization and/or dispersion. It would have been obvious to one of ordinary skill in the art at the time the invention was made to decrease the calcium ion concentration at or below 10 if at levels at and below 10 the composition was stable and in order to ensure that protein destruction and gelling of the food composition was prevented. To balance a known composition based on known effects and needs would

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have been obvious and routine determination of one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments filed July 29, 2009 have been fully considered but they are not persuasive.

Applicant argues that although Hojo does not teach of a chelating agent as instantly claimed. Applicant's argument is not convincing as Hojo teaches of ferrous gluconate and sodium iron citrate (Column 11 lines 4-8), which are both chelating agents as instantly claimed.

Application argues that although Hojo teaches of including the chelating agent, ferrous gluconate, Hojo does not require such, does not include it in the examples, and thus does not teach of the instantly claimed invention which requires a chelating agent, including gluconates. Applicant's argument is not convincing as Hojo teaches of including the chelating agent, ferrous gluconate or sodium iron citrate, in the food additive composition, such as instantly claimed (Column 11 lines 4-8). The fact that the chelating agent is not required or that it is not included in the examples does not limit the teachings of the reference. Exemplarily embodiments and preferred teachings do not limit the teachings of a reference.

Applicant argues that Hojo teaches the ferrous gluconate as a nutritional supplement and not a chelating agent and thus the reference does not teach of a chelating agent as instantly claimed. Applicant's argument is not convincing as (a) the claims recite a food additive composition with the chelating agent gluconate and citrates and the references of record teach of the instantly claimed food additive composition as stated above; (b) since the references of record teach of the same chelating agent as instantly claimed, the ferrous gluconate and citrates as taught by Hojo would inherently function the same as the gluconate and citrate chelating agent instantly claimed; and (c) applicant has provided no evidence otherwise or of unexpected results.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that

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any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). The examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, applicant's argument that there is no motivation to combine the teachings of Grossman and Hojo is not convincing as motivation was found in some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. Specifically, Hojo et al. (Hojo) teaches of a food additive composition which contains iron in the form of ferrous gluconate which is a chelating agent and calcium (Column 11 lines 4-8), however is silent to the amount of the ferrous gluconate and/or sodium iron citrate in the additive composition; Koumarios teaches that the food additive composition contains minerals, including iron and that the amount of the mineral in the food additive composition is determined based on the recommended daily dosage (Column 5 lines 8-17); Grossman teaches that the recommended daily amount of iron in 2001 for males ranged from 8-11mg per day and for females 8-18 mg per day (page 3); Klahorst, page 2, teaches that the recommended daily amount of calcium in 2001 was 1000-1300 mg per day; It would have been obvious to one of ordinary skill in the art at the time the invention was made to include an amount of the ferrous gluconate and/or sodium iron citrate and thus an amount of chelating agent in the additive composition depending on the recommended daily amounts of iron and the amount of iron desired in the final composition as taught by Koumarios; It would have been further obvious to one of ordinary skill in the art at the time the invention was made for the vitamins and minerals in the food additive,

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including calcium and iron, to be included in the full recommended daily amounts so that when consuming the food additive the consumers would not be required to take other additives to obtain complete daily fulfillment of the said vitamins and minerals; Thus, one would have been further motivated to include an amount of iron to calcium in the nutritional additive composition based upon the recommended daily amounts of iron and calcium, so that the nutritional additive would fulfill the requirements for both minerals simultaneously; and as the RDA of calcium: iron was 1300:8 or 100:0.6 to 1000:18 or 100:1.8 as taught by Grossman and Klahorst, at the time the invention was made, one would have been motivated to include 0.6-1.8 parts of ferrous gluconate and/or sodium iron citrate, i.e. an iron source, per 100 parts of calcium carbonate, i.e. a calcium source. Thus, the composition as taught by Hojo would comprise 0.6-1.8 parts of ferrous gluconate and/or sodium iron citrate which are chelating agents as instantly claimed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KELLY BEKKER whose telephone number is (571)272-2739. The examiner can normally be reached on Monday through Friday 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Kelly Bekker/
Examiner
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